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|  | **Title:** Data Management Plan (DMP) Template |
| **Project/Study name**: *Give study title to which this applies* |
| **Project/study ID:** *ClinicalTrials.gov Identifier:* |
| **Funder :**  |

**General information**

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| **Sponsor** |  |
| **Coordinating Investigator/Project Lead** |  |

**DMP Prepared by**

|  |  |
| --- | --- |
| **Name & Function** |  |
| **Signature & Date** |  |

**PRE-STUDY PHASE**

**1. Study setup**

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| **1.1 General information** |
| *Section that describes the aim and purpose of the DMP* |

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| **1.2 Study design**  |
| Section that describes a résumé of the study, type of data collected, with an overview of the data handling in the various study visits and activities. By preference it will hold flowcharts and a schematic overview of the visit schedule and related procedures. |

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| **1.3 Communication** |
| *Section that describes**briefly the communication of Data Management (DM) within the study/project, with clarification of the focal points for DM at the sponsor and the sites.*  |

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| **1.4 Documentation** |
| *Section that describes**briefly documentation handling of DM within the study/project* |

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| **1.5 Timelines** |

Table that list all essential milestones and timelines of DM within the study/project

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| **Milestone** | **Estimated Date** |
|  | dd/mm/yyyyy |

Create more rows if needed

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| **1.6 Study roles and responsibilities** |

*Table that lists all essential stakeholders of the study/project.*

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| **Study role** | **Name** | **Location (institute/site)** | **Responsibility** |
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Create more rows if needed

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|  **1.7 Confidentiality of study participant data** |
|  *Section that refers to essential principles and measures with regard to privacy and confidentiality of the study/project data* |

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| **2. Source Document/CRF Design (Data collection design)** |
| *Section on designing data collection tools or paper Case Report Forms (CFRs) for accurate and appropriate capture of data** *Data collection tool meeting the regulatory requirements*
* *Data collection tool meeting standards (e.g. CDASH)*
* *User friendliness of completion*
* *User friendliness for data entry*
* *Meeting the needs of the protocol*

*Section that refers to the SOP-WP3-2-CRF Design*  |

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| **3. Database/eCRF design** |
| *Describes more in detail the software or system used, with its various features & functionalities**Section that refers to the SOP-WP3-16-Database eCRF Design* |

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| **4. Database/System Validation** |
| *Describes in general the validation of the database or implemented system for performing data collection/entry, data management and data handling**This section focuses on two primary areas of responsibility:** *Validation of the software itself, meaning the responsibility of a data management organization to prospectively validate a (clinical) data management application that was purchased and installed for the purpose of performing data management tasks*
* *Validation of the system set-up for this particular study.*

*Section that refers to the SOP-WP3-17-System Validation, SOP WP3-22-Site Database Deployment, SOP WP3-23-Site Systems Upgrade and SOP WP3-24-Change Management.* |

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| **5. Database/Data Security** |
| *Section that describes the security measures taken to the data in the database/system** *Physical and technical safeguards*
* *Definition of access levels for users*
* *Authorization and withdrawal of database users (listing of these users)*

*Section that refers to the SOP-WP3-18-Information Security Policy* |

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| **6. Database backup** |
| *Section that describes the safeguarding of the dataset during a project** *Creation of backup copies of a database*
* *Implementation of a backup version when original is lost*

*Section that refers to the SOP-WP3-19-Data Backup & Disaster Recovery*  |

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| **7. DM Training** |
| *Section that describes all appropriate training for study staff in Data Management.** *Training confirmation form*
* *Template for user guidelines*
* *Periodic Training Plan*

*Section that refers to the SOP--WP3-3-Training & Capacity Building* |

**STUDY CONDUCT PHASE**

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| **8. Data Collection/Entry** |
| *Section that describes the process of entering data into the data capture system or database** *Target times for entry and verification*
* *Type of verification (double data entry, etc)*
* *Data entry conventions and guidelines*
* *Functions/roles involved*

*Section that refers to the SOP-WP3-6-Data Collection & Entry* |

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| **9. Data Validation/Review** |
| *Section that describes the process of verifying the accuracy, consistency and completeness of data entered into the database** *Manual checking procedures*
* *Automatic checking procedures (edit checks)*
* *Discrepancy handling/Query Management*

*Section that refers to the SOP-WP3-7-Data Validation & Review and SOP-WP3-21-Data Query Management* |

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| **10. Data Tracking** |
| *Section that describes the reception and tracking of data** *Tracking sheet or system*
* *Data flow diagram*
* *Monitoring and reporting on data flow: completing vs missing data*

*Section that refers to the SOP-WP3-10-Data Tracking* |

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| **11. Data/Medical Coding** |
| *Section that describes the coding data items in a clear and consistent manner** *Details of in-house coding conventions*
* *Details of (or referral to) external coding conventions (WHO, MedDRA,...)*
* *Details of tasks and responsibilities (Medical coder)*

*Section that refers to the SOP-WP3-8-Data Coding and Medical Coding* |

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| **12. SAE Reconciliation** |
| *Section that describes the process of cross-checking related data of serious adverse events (SAE), between the data management system (study database) and the safety system (SAE Reports).** *Description of procedure and timelines*
* *Details of tasks and responsibilities*
* *Checklist template*

*Section that refers to the SOP-WP3-9-SAE Reconciliation* |

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| **13. Data Storage** |
| *Section that describes the storage /retention of data:* * *Electronic storing system*
* *Paper retention*
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| **14. Data Transfer** |
| *Section that describes the transferring of data between stakeholders of a study/project.** *Considering confidentiality and appropriate measures*
* *Agree timelines of transfer*
* *Specifications of the format*
* *Description of the transfer process*

*Section that refers to the SOP-WP3-11-Data Transfer* |

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| **15. IT Support** |
| *Section that describes the IT Support and Documenting interventions by IT while supporting hard- or software** *Description of the problem + stakeholders*
* *Description of impact of actions on the study data*
* *Description of the solution and actions to be taken*

*Section that refers to the SOP-WP3-20-IT & Data Management Support* |

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| **16. Database Lock/Unlock** |
| *Section that describes the following:* *Locking the database to ensure security on completion of data entry and discrepancy resolution. Unlocking for authorized changes to a locked dataset.* * When to lock and unlock (quality checklist, acceptable error rate, reason for unlocking)
* Authorizations for locking and unlocking + template of approval form

*Section that refers to the SOP-WP3-12-Database Lock / Unlock* |

**POST STUDY PHASE**

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| **17. Archiving** |
| *Section that describes the archiving of project data to ensure security and confidentiality of the data, to allow comprehensive reconstruction of the completed work and to ensure regulatory requirements for retention DM Plan.* *Electronic archiving system: database; program* *Reference data (normal ranges, coding)* *Timing and length of archiving* *Submission and retrieval procedure**Section that refers to the SOP-WP3-13-Archiving* |

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| **18. Data Management Report** |
| *Section describing of a ‘final report on the DM activities of the study, with in particular quality issues and deviations of the DM plan.** *Reporting data processing details*
* *Reporting on quality efforts and issues*
* *List of unsolved discrepancies and edit checks*

*Section that refers to the SOP-WP3-14-Data Management Report* |

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| **19. Data Sharing** |
| *Section that describes the sharing of data, in particular to inform, to facilitate collaboration and to ensure regulatory , funder or publisher requirements.* * *type of data & system used*
* *Security and confidentiality measurements*
* *Agreements (what data; when; process. format)*
* *Description of metadata*

*Section that refers to the SOP-WP3-15-Data Sharing* |

**Revision history**

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| --- | --- |
| **Version n° & Date** | Description |
|  |  |

**Approved by**

|  |  |
| --- | --- |
| **Project Lead\*****Name & Function** |  |
| **Signature & Date** |  |

\*Adapt ( Coordinating Investigator and/or PI) and create a row more if needed